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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,608	11/14/2001	Barbara Sheila Goldberg	1223.0050000	7303

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EXAMINER

PRUNNER, KATHLEEN J

ART UNIT	PAPER NUMBER
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3751

DATE MAILED: 09/10/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/936,608

Applicant(s)
Goldberg et al.

Examiner
Kathleen J. Prunner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 2, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Nov 14, 2001 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, (A) the dispensing container and applicator, as called for by claim 1, and (B) the outer sealed container, as called for by claim 11, must be shown or the features canceled from the claims. No new matter should be presented or it will not be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign mentioned in the description: **26B** (note page 5, line 12, of the specification). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because, in Fig. 5, the three different parts should be bracketed together to indicate that they form a single entity. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. Applicant is required to submit a proposed drawing correction **in reply to this Office action**. Any proposal by the applicant for amendment of the drawing to cure defects **MUST** be embodied in a **SEPARATE LETTER to the Draftsman**. See MPEP §608.02(r).

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Specification

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. The sheet should only contain the Abstract and be numbered as page 15 so that it can be properly placed in the specification.
6. The following informalities in the specification are noted: the terminology used in the description of the invention summarized on pages 2-4 is inconsistent with the terminology used in the detailed description given on pages 5-11. Appropriate correction, i.e., consistent terminology, is required.
7. The following informalities in the claims are noted: (A) in claim 1, on line 1, "an adhesive" (second occurrence) should be deleted since the patch is only made adhesive by the adhesive surface called for on line 2; and (B) in claim 11, line 2, "adhesive" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
9. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 calls for "a dispensing container", "an applicator" or "applicator means", and the substance "to be dispensed over the area to be treated via the applicator means"; however, the specification fails to describe what structure constitutes the dispensing container and the applicator and/or applicator means as called for by claim 1. Also, claim 11 calls for "an outer sealed container" as well as the

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“dispensing container”; however, the specification fails to describe such containers as called for by this claim.

10. Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using a removable peeling strip for sealing off the apertures when apertures constitute the release agent (note lines 22-24 on page 5) and for omitting the peeling strip when rupturing zones are formed (note lines 3-6 on page 8), does not reasonably provide enablement for a removable sealing strip to be used regardless of whether the release agent includes at least one aperture or rupturable zone, as called for by claims 5 and 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claim 1 contains a term lacking proper antecedent basis. The claim recites the limitation “the applicator means” in line 12. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 3 contains a term lacking proper antecedent basis. The claim recites the limitation “the backing means” in line 4. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 4 contains terms lacking proper antecedent basis. The claim recites the limitations “the peelable backing means” in line 2 and “the backing means” in line 4. There is insufficient antecedent basis for these limitations in the claim.

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16. Claim 6 contains a term lacking proper antecedent basis. The claim recites the limitation "the non-adhering zones" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-6 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Sabatano. Sabatano discloses an adhesive dispensing arrangement having all the claimed features including a patch (constituted by tape 11) for covering the area to be treated, the patch being provided with an adhesive surface 12 for allowing the patch to stick or adhere to the surface (note lines 33-36 in col. 2), a peelable backing (constituted by cover 22 and tape 18) covering the adhesive surface (note Fig. 1), a dispensing container (constituted by envelope 14) being sandwiched between the adhesive surface 12 and the peelable backing and housing a substance (constituted by the antiseptic jelly 15) to be dispensed, an applicator (constituted by gauze pad 13) arranged to facilitate the application of the substance 15 over the area to be treated, and a release agent (constituted by outlet opening 16) arranged to cause the dispensing container 14 to open on removal of the backing 22 for releasing the substance 15. With respect to claim 2, Sabatano also discloses that the applicator 13 is maintained apart from the substance 15 within the container 14 and is arranged to be impregnated with the substance 15 only after the container 14 has ruptured with the applicator 13 being interposed between the container 14 and the peelable backing (note Fig. 2). With respect to claim 3, Sabatano

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additionally discloses that the applicator includes at least one absorbent pad 13 secured to the patch 11 along at least one marginal adhering zone with a non-adhering zone (constituted by the top surface thereof as shown in Fig. 2) being interposed between the dispensing container 14 and the backing 22 (note Fig. 2) for receiving the substance 15 to be dispensed from the container 14 after outlet opening 16 is exposed (note lines 20-29 in col. 2). With regard to claim 4, Sabatano further discloses that the release agent (constituted by outlet opening 16) is adhesively secured to the peelable backing portion 18 such that tape 18 is peeled away with the backing portion 22 to expose the outlet opening 16 (note lines 20-29 in col. 2). With regard to claim 5, Sabatano additionally discloses that the release agent includes at least one aperture or opening 16 and a removable sealing strip constituted by the tab end C being arranged to expose the opening 16 on removal of the tab end C. With regard to claim 6, Sabatano further discloses that the sealing strip C extends between the container 14 and the non-adhered zones of the pad 13 whereby the pad 13 is arranged temporarily to splay outwardly to allow the sealing strip to exit as it is peeled away from the container 14 (note Fig. 2). With respect to claim 11, Sabatano also discloses that patch 11 and the peelable backing define an outer sealed container within which the dispensing container 14 is housed (note Fig. 2). With respect to claim 12, Sabatano further discloses that the adhesive dispensing arrangement is in the form of a bandage (note line 4 in col. 1) for medical application with the substance 15 being a medicament (note lines 5-9 in col. 1). With regard to claim 13, Sabatano additionally discloses that substance 15 is used to treat selected areas (note lines 14-17 in col. 1) and is an antiseptic constituting a chemical treatment (note line 67 in col. 1).

19. Claims 1 and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi et al. (EP 734,722). Yamaguchi et al. disclose an adhesive dispensing arrangement having all the claimed features including a patch (constituted by layer 5) for covering the area to be treated, the patch being provided with an adhesive surface (note line 17 in col. 7) for allowing the patch to stick

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or adhere to the surface (note lines 31-32 in col. 7), a peelable backing (constituted by layer 2) covering the adhesive surface (note Fig. 1), a dispensing container (constituted by storage layer 4) being sandwiched between the adhesive surface and the peelable backing and housing a substance (note lines 16-24 in col. 4) to be dispensed, an applicator constituted by layer 8 (note Fig. 9) arranged to facilitate the application of the substance over the area to be treated, and a release agent (constituted by releasable liner layer 6) arranged to cause the dispensing container 4 to open on removal of the backing 2 for releasing the substance. With respect to claim 8, Yamaguchi et al. also disclose that the applicator is housed within the container 4 and is impregnated with the substance with which it is stored (note lines 54-55 in col. 7). With respect to claim 9, Yamaguchi et al. further disclose that release agent comprises a rupturing aid (constituted by notches 7) for breaching or removing a rupturable zone on the container 4 so as to provide an opening in the container 4 (note Fig. 1). With respect to claim 10, Yamaguchi et al. additionally disclose that container 4 comprises a rupturable sachet (note Fig. 1), the rupturing zone comprises a line of weakness (at notches 7) arranged to facilitate the tearing away of a topmost wall of the sachet, and the rupturing aid is constituted by the extent to which bonding between the top wall of the sachet and a sealing or cover strip exceeds the line of weakness bonding (note lines 7-28 in col. 6 and lines 25-31 in col. 7). With respect to claim 11, Yamaguchi et al. also disclose that patch and the peelable backing define an outer sealed container within which the dispensing container 4 is housed (note Fig. 1a). With respect to claim 12, Yamaguchi et al. further disclose that the adhesive dispensing arrangement is in the form of a bandage (note lines 16-21 in col. 9) for medical application with the substance being a medicament (note lines 25-59 in col. 4). With regard to claim 13, Yamaguchi et al. additionally discloses that substance is used to treat selected areas (note lines 6-9 in col. 9) and is a drug constituting a chemical treatment (note lines 1-41 in col. 5).

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Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sabatano in view of Yamaguchi et al. (EP 734,722). Although Sabatano fails to disclose that more than one pad can be provided, attention is directed to Yamaguchi et al. who disclose another adhesive dispensing arrangement in which the patch can contain two or more absorbable drugs if such is necessary for proper treatment (note lines 1-2 in col. 5) of the patient. It would have been obvious to one of ordinary skill in the adhesive dispensing arrangement art, at the time the invention was made, to provide the bandage/patch of Sabatano with two or more medicament/drug impregnated pads in view of the teachings of Yamaguchi et al. in order to provide proper treatment of the patient's wound if such is necessary.

Conclusion

22. The Examiner is advising attorneys to FAX any response due to Office actions. The U. S. Patent and Trademark Office (USPTO) is experiencing major delays in matching up papers that were mailed. Due to the Anthrax issue, any mail sent to the USPTO is automatically sent to an irradiation center in Virginia. It has been found that the irradiation process makes papers too brittle to handle. Therefore, the irradiation center has to further copy each paper. The originally filed irradiated papers are then placed in a sealed envelope and put in the associated file. After this irradiation process, the "papers" are then sent to the Office where they are matched with the file. This entire procedure

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causes months in delays due to the quantity of mailed received. Therefore, it is suggested that any response be sent by FAX especially if a time limit is critical. The FAX number for the technical center where this file is located is given in the paragraph below.

23. Any inquiry concerning this communication from the examiner should be directed to Examiner Kathleen J. Prunner whose telephone number is 703-306-9044. Although the examiner participates in the maxi-flex program, she can usually be reached Monday through Friday from 5:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory L. Huson, can be reached on 703-308-2580. The FAX phone number for the organization where this application is assigned is 703-308-7766.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is 703-308-0861.



Kathleen J. Prunner:kjp

September 4, 2002



TIMOTHY L. MAUST
PRIMARY EXAMINER